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Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. **Docket Number (Optional)** PRE-APPEAL BRIEF REQUEST FOR REVIEW 54459-237216 I hereby certify that this correspondence is being deposited with the Application Number Filed United States Postal Service with sufficient postage as first class mail February 27, 2002 10/084,240 in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] First Named Inventor on November 14, 2005 RAYMOND R. RACKLEY Signature Art Unit Examiner Typed or printed 3763 THANH, LOAN H. Name Jackie O'Neil Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request. This request is being filed with a notice of appeal. The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided. I am the applicant/Inventor. assignee of record of the entire interest. John L. Crimmins See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. Typed or printed name (Farm PTO/SB/96) attorney or agent of record. (612) 766-7749 Registration number 51,589 Telephone number attorney or agent acting under 37 CFR 1.34. Registration number November 14, 2005 Date \*Total of forms are submitted.

This collection of Information Is required by 35 U.S.C. 132. The Information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1430, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

## Pre-Appeal Request for Review

Applicants respectfully submit that claims 1, 5, 6, 12-14, and 16 are not obvious under 35 U.S.C. Section 103(a) in view of U.S. Patent No. 5,792,478 to Lawin et al. ("Lawin"), U.S. Patent No. 5,893,839 to Johnson ("Johnson") and U.S. Patent No. 6,258,067 to Hill ("Hill"). Applicants' position with respect to this rejection is set forth in Applicants' Amendment dated June 30, 2005 (the "Amendment"). Additional remarks with respect to this rejection are provided below.

## Additional Remarks

In the Final Office Action dated September 22, 2005, the Examiner stated that Applicants' arguments set forth in the Amendment are directed to functional language in the claim, and that the device reported in Johnson is capable of performing Applicants' stated function.

Applicants respectfully disagree with the Examiner's characterization of Applicants' assertions in the Amendment. Independent claims 1 and 12 each recite that the device includes a needle having a length between about 1.5 and 5 inches, and an arcuate segment formed by about a 15 degree bend located within a portion of the needle closest to a tip of the needle. None of the cited references, including Johnson, report a device having each of these structural limitations.

Because these claim features are not taught in any of the cited references, the Examiner must set forth a prima facie case that a person of skill in the art would be motivated to modify the device reported in Johnson accordingly. However, for the reasons set forth in the Amendment, there would have been no motivation to modify the device reported in Johnson to provide the claimed length and bend, even if Johnson teaches a needle having a length and arc which may be varied. In particular, the device reported in Johnson is intended for use in vascular treatments, however, there is no suggestion in any of the cited art references that the claimed length and bend angle would be suitable for use in such

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procedures. Indeed, Johnson does not even appear to report a range of bend angles suitable for use in such vascular procedures.

Applicants further disagree with the Examiner's assertion that the Johnson device is necessarily capable of performing the intended use. As previously noted, Johnson expressly reports that the device as being suitable for use in vascular procedures, and is entirely silent with respect to urethral bulking procedures. Therefore, there is no suggestion that the reported device is capable of being used in urethral bulking procedures.

Based on the foregoing arguments, Applicants assert that all appealed claims are allowable over the prior art of record. Applicants respectfully request review of the arguments set forth herein and allowance of claims 1,5-6,12-14, and 16.

Sincerely,

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Dated: November 14, 2005

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